



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002
October 17, 2014

NOVA BIOMEDICAL CORPORATION

PAUL W. MCDONALD

CHIEF QUALITY ASSURANCE AND REGULATORY AFFAIRS OFFICER

200 PROSPECT ST

WALTHAM MA 02454

Re: K142220

Trade/Device Name: Stat Profile® Prime ABG Analyzer System,
Stat Profile® Prime Auto QC Cartridge ABG,
Stat Profile® Prime Ampuled Control ABG/CCS,
Stat Profile® Prime Calibrator Cartridge ABG

Regulation Number: 21 CFR 862.1120

Regulation Name: Blood gases (PCO₂, PO₂) and blood pH test system

Regulatory Class: II

Product Code: CHL, JIX, JJS

Dated: August 29, 2014

Received: September 2, 2014

Dear Mr. Paul W. McDonald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (*if known*)

K142220

Device Name

Stat Profile® Prime ABG Analyzer System, Stat Profile Prime Auto QC Cartridge ABG, Stat Profile Prime Ampuled Control ABG/CCS, Stat Profile Prime Calibrator Cartridge ABG

Indications for Use (*Describe*)

The Stat Profile Prime ABG Analyzer System is intended for in vitro diagnostic use by health care professionals in clinical laboratory settings for the quantitative determination of pH, PCO₂, and PO₂ in heparinized whole blood.

PCO₂, PO₂, pH: Whole blood measurement of blood gases is used in the diagnosis and treatment of life threatening acid-base disturbances.

Stat Profile Prime Auto QC Cartridge ABG is a quality control material intended for in vitro diagnostic use by healthcare professionals for monitoring the performance of the Stat Profile Prime ABG Analyzer.

Stat Profile Prime Ampuled Control ABG/CCS is a quality control material intended for in vitro diagnostic use by healthcare professionals for monitoring the performance of Stat Profile Prime ABG Analyzer.

Stat Profile Prime Calibrator Cartridge ABG is intended for the calibration of pH, PCO₂, and PO₂, using the Stat Profile Prime ABG Analyzer.

Type of Use (*Select one or both, as applicable*)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1. Submitter

510(K) Owner: Nova Biomedical Corporation
Registration Number: 1219029
Address: 200 Prospect St.
Waltham, MA 02454
Phone: 781-894-0800
Fax Number: 784-891-4806
Contact Person: Paul W. MacDonald
Date Prepared: October 3, 2014

2. Device:

Proprietary Name: Stat Profile® Prime ABG Analyzer System, Stat Profile Prime Auto QC Cartridge ABG, Stat Profile Prime Ampuled Control ABG/CCS, Stat Profile Prime Calibrator Cartridge ABG

Common or Usual Name: Blood gases (PCO₂, PO₂) and blood pH Test System

Classification Name: Multiple

Classification Names:	Class No.	Reg. No.	Class
Blood Gases and Blood pH system	75CHL	862.1120	II
Calibrators	75JIX	862.1150	II
Quality Control Materials	75JJS	862.1660	I

Product Codes: CHL, JIX, JJS

3. Predicate Device:

K131703 - Stat Profile® Prime CCS Analyzer System, Stat Profile Prime Auto QC Cartridge CCS, Stat Profile Prime Ampuled Control ABG/CCS, Stat Profile Prime Calibrator Cartridge CCS/CCS Comp

4. Device Description:

The Stat Profile® Prime ABG Analyzer System is a small, low cost blood gas analyzer for laboratory use. The sensors and flow path have been integrated into one replaceable microsensor card, which is replaced periodically according to usage. The product, consumables, installation instructions and packaging are designed for easy customer installation. The Stat Profile® Prime ABG Analyzer System is not intended for Point of Care Use.

Whole blood specimens are aspirated into the analyzer's microsensor card from syringes, tubes, or capillary blood collection devices using a peristaltic pump and a sampling probe. The disposable microsensor card contains the analytical flow path and the measurement sensors (PCO₂, PO₂, and pH). Once the analysis measurement is complete, the whole blood specimen is automatically flushed out of the microsensor card flow path and into a self-contained waste collection bag contained within the disposable calibrator cartridge.

As in the predicate Stat Profile® Prime CCS Analyzer System (K131703), the Stat Profile Prime ABG Analyzer will have an enhanced test menu and multiple quality control options. Both traditional Internal and External liquid QC shall be offered, as well as an on-board Quality Management System (QMS), an electronic monitoring approach that insures the analyzer is working properly.

As with the predicate, the Stat Profile Prime ABG Analyzer is microprocessor-based and incorporates:

- traditional sensor technology to measure blood pO₂
- ion selective electrode technology to measure PCO₂ and, pH

Liquid quality control materials are available as internal auto-cartridge quality control packs and as external ampules. The sampling, calibration and quality control functions are fully automated.

Internal Calibration standards with dissolved gases are provided in sealed pouches eliminating the need for users to calibrate the blood gas electrodes using external compressed gas cylinders. The Calibration Cartridges contain aqueous solutions within individual flexible bags housed in a cardboard box and a flexible waste bag. Each bag includes a fitment with a septa that is pierced during the insertion of the cartridge into the analyzer.

The external glass ampule controls contain a buffered bicarbonate solution with a known pH level. The solutions are equilibrated with known levels of O₂, CO₂, and N₂. Each ampule contains 1.7 ml volume.

The internal auto QC cartridge consists of 3 flexible bags within a cardboard carton. Each bag contains an aqueous quality control material for monitoring the measurement of pH, PCO₂ and PO₂. The aqueous quality control materials are composed of a buffered bicarbonate solution, with a known pH. Solutions are equilibrated with known levels of O₂, CO₂, and N₂. Each bag contains a minimum volume of 100 mL.

The Stat Profile Prime ABG Analyzer accepts Lithium heparin whole blood sample from syringes, open tubes, small cups, and capillary tubes. The minimum sample size for both syringe and capillary samples analysis is 50 µL.

Measured Parameters:

The Stat Profile Prime ABG Analyzer measures pH, PCO₂, and PO₂.

5. Indications for Use:

The Stat Profile Prime ABG Analyzer System is intended for in vitro diagnostic use by health care professionals in clinical laboratory settings for the quantitative determination of pH, PCO₂, and PO₂ in heparinized whole blood.

pH, PCO₂, PO₂: Whole blood measurement of blood gases is used in the diagnosis and treatment of life-threatening acid-base disturbances.

The **Stat Profile Prime Auto QC Cartridge ABG** is a quality control material intended for in vitro diagnostic use by healthcare professionals for monitoring the performance of the Stat Profile Prime ABG Analyzer.

The **Stat Profile Prime Ampuled Control ABG/CCS** is a quality control material intended for in vitro diagnostic use by healthcare professionals for monitoring the performance of Stat Profile Prime ABG Analyzer.

The **Stat Profile Prime Calibrator Cartridge ABG** is intended for the calibration of pH, PCO₂, and PO₂ using the Stat Profile Prime ABG Analyzer.

6. Comparison of Technological Characteristics with the predicate device:

Both the Stat Profile® Prime ABG Analyzer System and the predicate Stat Profile® Prime CCS Analyzer System (K131703) are small, low cost blood gas analyzer for laboratory use. The sensors for measurement of pH, PCO₂, and PO₂ are identical. They both use disposable sensor cartridges, controls and calibrator packs. A comparison of the similarities and differences between the two systems is provided in the following tables:

Comparison of Stat Profile® Prime ABG Analyzer to the predicate - Similarities		
Characteristic	Predicate: K131703 Stat Profile® Prime CCS Analyzer	Proposed: Stat Profile® Prime ABG Analyzer
Indication for Use	pH, PCO ₂ , PO ₂ : Whole blood measurement of blood gases is used in the diagnosis and treatment of life-threatening acid-base disturbances.	Same
Acceptable Samples	Lithium heparinized whole blood from syringes, open tubes, small cups, and capillary tubes.	Same
Measurement Range		
pH	6.500-8.000	Same
PCO ₂	3.0 -200 mmHg	Same
PO ₂	5-765 mmHg	Same
Principles of Measurement		
pH	Hydrogen ion-selective sensor	Same
PCO ₂	Severinghaus-type sensor	Same
PO ₂	Polarographic Clark-type sensor	Same
Touch Screen	5.7" VGA full color display with LED backlight and integrated touch panel	Same
Menu	Fully configurable test menu based on above sensors	Same
Bar Code Scanner	Internal Integrated 1D/2D	Same
Printer	2" Roll, Thermal Transfer	Same
Pump	Peristaltic Pump w/ Pressure Plate, TPE Tubing (Pharmed BPT)	Same
Analog Board	Precision low level analog front end w/ amperometric and potentiometric amplifiers, air detector circuitry and temperature control circuitry	Same

Comparison of Stat Profile® Prime ABG Analyzer to the predicate - Differences		
Characteristic	Predicate: K131703 Stat Profile® Prime CCS Analyzer	Proposed: Stat Profile® Prime ABG Analyzer
Intended Use	The Stat Profile Prime CCS Analyzer System is intended for in vitro diagnostic use by health care professionals in clinical laboratory settings for the quantitative determination of pH, PCO ₂ , PO ₂ , Hct, Na ⁺ , K ⁺ , Cl ⁻ , iCa, and Glu (Glucose), in heparinized whole blood.	The Stat Profile Prime ABG Analyzer System is intended for in vitro diagnostic use by health care professionals in clinical laboratory settings for the quantitative determination of pH, PCO ₂ , and PO ₂ in heparinized whole blood.
Indication For Use	Hct	Whole blood measurements of the packed red cell volume of a blood sample are used to distinguish normal from abnormal states, such as anemia and erythrocytosis (an increase in the number of red cells).
	Na ⁺	Sodium measurement is used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, or diseases involving electrolyte imbalance.
	K ⁺	Potassium Measurement is used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high potassium levels.

Comparison of Stat Profile® Prime ABG Analyzer to the predicate - Differences			
Characteristic	Predicate: K131703 Stat Profile® Prime CCS Analyzer	Proposed: Stat Profile® Prime ABG Analyzer	
	Cl-	Chloride measurement is used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.	N/A
	iCa	Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).	N/A
	Glu	Glucose measurement is used in the diagnosis and treatment of carbohydrate metabolism disturbances including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.	N/A
Sample Volumes	100µL (syringe and capillary)	50µL (syringe and capillary)	
Measurement Range			
Hct	12%-70%	N/A	
Na+	80-200 mmol/L	N/A	
K+	1.0-20.0 mmol/L	N/A	
Cl-	50-200 mmol/L	N/A	
iCa (Ca++)	0.20-2.70 mmol/L	N/A	
Glu	15-500 mg/dL	N/A	
Principles of Measurement			
Hct	Impedance sensor	N/A	
Na+	Sodium ion-selective sensor	N/A	
K+	Potassium ion-selective sensor	N/A	
Cl-	Chloride ion-selective sensor	N/A	
iCa (Ca++)	Calcium ion-selective sensor	N/A	
Glu	Glucose Oxidase Enzymatic sensor	N/A	

Comparison of Stat Profile® Prime Calibrator Cartridge ABG to the predicate - Similarities		
Characteristic	Predicate: K131703 Stat Profile Prime Calibrator Cartridge CCS	Proposed: Stat Profile Prime Calibrator Cartridge ABG
Configuration	2 level calibration standards per analyte, and reference solution	Same
Packaging	Liquid in Mylar bags inside cardboard container. Includes a waste collection bag. Self-contained, disposable packaging.	Same

Comparison of Stat Profile® Prime Calibrator Cartridge ABG to the predicate - Differences		
Characteristic	Predicate: K131703 Stat Profile Prime Calibrator Cartridge CCS	Proposed: Stat Profile Prime Calibrator Cartridge ABG
Indication For Use	The Stat Profile Prime Calibrator Cartridge CCS is intended for the calibration of pH, PCO ₂ , PO ₂ , Hct, Na ⁺ , K ⁺ , Cl ⁻ , iCa, and Glucose using the Stat Profile Prime CCS Analyzer.	The Stat Profile Prime Calibrator Cartridge ABG is intended for the calibration of pH, PCO ₂ , and PO ₂ , using the Stat Profile Prime ABG Analyzer.

Comparison of Stat Profile Prime Auto QC Cartridge ABG to the predicate - Similarities		
Characteristic	Predicate: K131703 Stat Profile Prime Auto QC Cartridge CCS	Proposed: Stat Profile Prime Auto QC Cartridge ABG
Configuration	3 level aqueous electrolyte, metabolite and gas solutions.	Same
Packaging	Cartridge: Solution in Mylar bags inside cardboard container. Includes a waste collection bag. Self-contained, disposable packaging.	Same

Comparison of Stat Profile Prime Auto QC Cartridge ABG to the predicate - Differences		
Characteristic	Predicate: K131703 Stat Profile Prime Auto QC Cartridge CCS	Proposed: Stat Profile Prime Auto QC Cartridge ABG
Indication For Use	The Stat Profile Prime Auto QC Cartridge CCS is a quality control material intended for in vitro diagnostic use by healthcare professionals for monitoring the performance of the Stat Profile Prime CCS Analyzer.	The Stat Profile Prime Auto QC Cartridge ABG is a quality control material intended for in vitro diagnostic use by healthcare professionals for monitoring the performance of the Stat Profile Prime ABG Analyzer.

Comparison of Stat Profile Prime Ampuled Control ABG/CCS to the predicate - Similarities		
Characteristic	Predicate: K131703 Stat Profile Prime Ampuled Control ABG/CCS	Proposed: Stat Profile Prime Ampuled Control ABG/CCS
Configuration	3 level aqueous electrolyte, metabolite and gas solutions.	Same
Packaging	Ampules: Each glass ampule contains 1.7 ml volume.	Same

Comparison of Stat Profile Prime Ampuled Control ABG/CCS to the predicate - Differences		
Characteristic	Predicate: K131703 Stat Profile Prime Ampuled Control ABG/CCS	Proposed: Stat Profile Prime Ampuled Control ABG/CCS
Indication For Use	The Stat Profile Prime Ampuled Control ABG/CCS is a quality control material intended for in vitro diagnostic use by healthcare professionals for monitoring the performance of Stat Profile Prime CCS Analyzer.	The Stat Profile Prime Ampuled Control ABG/CCS is a quality control material intended for in vitro diagnostic use by healthcare professionals for monitoring the performance of Stat Profile Prime ABG Analyzer and the Stat Profile Prime CCS Analyzer.

7. Summary of Performance Testing:

Bench testing was completed to demonstrate that the Stat Profile Prime ABG Analyzer is substantially equivalent in performance, safety and efficacy to the Stat Profile Prime CCS Analyzer System.

7.1. Method Comparison Studies

Whole Blood Patient Specimens:

Discarded heparinized arterial whole blood specimens from hospital patients were analyzed in duplicate on the three test analyzers and two reference analyzers. In order to cover the hard to find sample range, venous whole blood from male and female donors was tonometered to cover the analytical measurement range for all analytes. These samples were identified and noted as altered samples in the results. The number of data points (N) varies for each parameter due to error, calibration status, or insufficient sample volume to complete analysis.

Syringe Samples: A minimum of 150 whole blood specimens were analyzed for pH, pCO₂ and pO₂. The samples were analyzed on each of the test analyzers and on the Stat Profile Prime CCS Comp analyzers and compared for each parameter. The first replicate test analyzer result from each test system was compared to the average of the two results from the comparative method.

Results: The data for the whole blood method comparison of the Stat Profile Prime ABG vs. the Stat Profile Prime CCS Comp is summarized in Table 1 and contains the following information:.

- slope and intercept of the fitted line
- total number of points used in the regression
- bias calculated from the regression line at medical decision levels
- range of data
- correlation coefficient
- number of altered samples

Table 1: Stat Profile Prime ABG vs. Stat Profile Prime CCS Comp Whole Blood Method Comparison

Individual Analyzer Performance Data First Replicate vs. Average of Reference Analyzers							
Parameter	Analyzer	total # specimens	# altered specimens	specimen range	Slope	Intercept	r
pH	#1	170	17	6.771 - 7.796	0.9987	0.0042	0.9971
	#2	175	14	6.768 - 7.789	0.9933	0.0431	0.9978
	#3	187	18	6.776 - 7.799	0.9937	0.0433	0.9986
pCO ₂ (mmHg)	#1	161	16	22.7 - 174.1	0.9899	0.7042	0.9972
	#2	163	12	24.0 - 185.4	0.9834	0.5996	0.9975
	#3	168	10	22.4 - 178.1	0.9923	1.8045	0.9940
pO ₂ (mmHg)	#1	153	10	8.8 - 728.3	1.0141	-0.6862	0.9975
	#2	165	11	10.2 - 677.6	1.0074	0.8237	0.9985
	#3	165	9	9.3 - 687.1	1.0080	0.7950	0.9991

7.2. Precision/Reproducibility Studies

Run to Run Precision

Whole Blood: Estimates of the run to run precision were determined for each of the Stat Profile Prime analyzers by analyzing a single whole blood sample in triplicate over ten (10) separate runs during a single day. The run to run precision was measured on blood analyzed from a syringe and also from capillary containers. The analyzers were re-calibrated before each triplicate run.

Results: Estimates of the run to run precision were determined for the Stat Profile Prime ABG analyzers for blood analyzed in syringe and capillary modes. Statistical analysis for each parameter included mean, SD, CV% (pH excluded), and N for all analyzers. The data is summarized in Table 2

Table 2: Stat Profile Prime ABG Whole Blood Run to Run Precision Summary

Syringe Mode pH Precision Data					
Analyzer	N	Mean	Standard Deviation	CV%	Target
#1	30	7.339	0.010		
#2	30	7.337	0.007		7.332
#3	30	7.336	0.009		
pCO ₂ Precision Data					
Analyzer	N	Mean	Standard Deviation	CV%	Target
#1	30	49.3	1.2	2.4	51.2
#2	30	49.6	1.2	2.5	mmHg
#3	30	50.0	1.2	2.3	
pO ₂ Precision Data					
Analyzer	N	Mean	Standard Deviation	CV%	Target
#1	30	34.2	0.5	1.4	32.9
#2	30	35.1	0.5	1.3	mmHg
#3	30	36.6	0.5	1.3	
Capillary Mode pH Precision Data					
Analyzer	N	Mean	Standard Deviation	CV%	Target
#1	30	7.205	0.006		
#2	30	7.204	0.007		7.195
#3	30	7.176	0.005		
pCO ₂ Precision Data					
Analyzer	N	Mean	Standard Deviation	CV%	Target
#1	30	73.0	2.2	3.0	75.3
#2	30	74.1	2.6	3.5	mmHg
#3	30	69.7	2.4	3.5	
pO ₂ Precision Data					
Analyzer	N	Mean	Standard Deviation	CV%	Target
#1	30	61.7	0.7	1.2	59.8
#2	30	64.2	1.2	1.8	mmHg
#3	30	61.6	0.7	1.1	

Control Solutions: Estimates of the run to run precision were determined for each of the Stat Profile Prime analyzers by analyzing Stat Profile Prime Quality Control solutions (3 levels for each parameter in QC mode) in duplicate, two runs per day for a total of forty (40) runs. The data is summarized in Table 3

Results: Estimates of the run to run precision were determined for the Stat Profile Prime ABG analyzers for each level of Quality Control. Statistical analysis for each parameter included pooled mean, Sr, ST, CV% (pH excluded), and N for all analyzers.

Table 3: Stat Profile Prime ABG Quality Control Run to Run Precision Summary

pH Precision Data							
Sample	Pooled Mean	N	Within run SD (Sr)	Within run % CV	Total imprecision SD (St)	Total Imprecision %CV	Target Range
QC Level 1	7.151	240	0.001	---	0.004	---	7.134-7.184
QC Level 2	7.358	240	0.000	---	0.006	---	7.342-7.392
QC Level 3	7.569	240	0.000	---	0.008	---	7.549-7.599
pCO ₂ Precision Data							
Sample	Pooled Mean (mm Hg)	N	Within run SD (Sr)	Within run % CV	Total imprecision SD (St)	Total Imprecision %CV	Target Range mmHg
QC Level 1	57.0	240	0.33	0.58	0.92	1.61	52.2-67.2
QC Level 2	39.7	240	0.27	0.68	0.63	1.59	34.2-45.2
QC Level 3	24.0	240	0.19	0.79	0.80	3.33	18.9-27.9
pO ₂ Precision Data							
Sample	Pooled Mean (mm Hg)	N	Within run SD (Sr)	Within run % CV	Total imprecision SD (St)	Total Imprecision %CV	Target Range mmHg
QC Level 1	57.4	240	0.43	0.75	2.22	3.87	50.0-66.0
QC Level 2	101.5	240	0.29	0.29	2.57	2.53	90.8-106.8
QC Level 3	137.2	240	0.34	0.25	3.51	2.56	125.7-149.7

Within Run Precision

One run of each, 20 replicates per run, of the following materials was performed:

- Whole Blood – analyzed from syringe
- Whole Blood – analyzed from capillary containers
- Stat Profile Prime Quality Control Level 1
- Stat Profile Prime Quality Control Level 2
- Stat Profile Prime Quality Control Level 3

Results: The average, SD, CV% and N for each analyzer, sample type, and parameter was calculated. The data is summarized in Table 4.

Table 4: Stat Profile Prime ABG With-in Run Precision – Whole Blood

Stat Profile Prime ABG With-in Run Precision					
Whole Blood Syringe Mode					
Parameter	n = 20	Analyzer # 1	Analyzer # 2	Analyzer # 3	Target
pH	Mean SD	7.367 0.005	7.356 0.004	7.370 0.004	7.359
pCO ₂ (mmHg)	Mean SD CV%	40.7 0.4 1.1	41.9 0.4 0.9	41.0 0.5 1.1	40.8
pO ₂ (mmHg)	Mean SD CV%	86.2 1.2 1.4	88.6 1.2 1.3	86.5 1.2 1.3	90.2
Whole Blood Capillary Mode					
Parameter	n = 20	Analyzer # 1	Analyzer # 2	Analyzer # 3	Target
pH	Mean SD	7.349 0.005	7.335 0.005	7.348 0.004	7.351
pCO ₂ (mmHg)	Mean SD CV%	39.3 0.6 1.5	40.9 0.7 1.7	39.8 0.6 1.5	40.4
pO ₂ (mmHg)	Mean SD CV%	92.4 1.8 2.0	94.0 1.8 1.9	92.9 1.9 2.0	91.5

Results: The average, SD, CV% and N for each analyzer for each QC level and parameter was calculated. The pooled average, SD, CV% and N from all 3 analyzers for each QC level and parameter was calculated. The data is summarized in Table 5.

Table 5: Stat Profile Prime ABG With-in Run Precision - Controls

On Board Quality Control Level 1						
Parameter	n = 20	Analyzer # 1	Analyzer # 2	Analyzer # 3	Pooled	Target Range
pH	Mean	7.149	7.146	7.150	7.148	7.134-7.184
	SD	0.001	0.001	0.001	0.002	
pCO ₂ (mmHg)	Mean	58.0	58.1	57.6	57.9	52.2-67.2
	SD	0.4	0.4	0.3	0.5	
	CV%	0.8	0.7	0.6	0.8	
pO ₂ (mmHg)	Mean	58.3	62.1	62.1	60.8	50.0-66.0
	SD	0.6	0.3	0.3	1.8	
	CV%	1.1	0.5	0.5	3.0	
On Board Quality Control Level 2						
Parameter	n = 20	Analyzer # 1	Analyzer # 2	Analyzer # 3	Pooled	Target Range
pH	Mean	7.355	7.350	7.355	7.353	7.342-7.392
	SD	0.001	0.001	0.001	0.002	
pCO ₂ (mmHg)	Mean	40.5	40.7	40.7	40.6	34.2-45.2
	SD	0.5	0.4	0.3	0.4	
	CV%	1.2	1.0	0.9	1.0	
pO ₂ (mmHg)	Mean	97.2	101.5	97.8	98.8	90.8-106.8
	SD	0.5	0.3	0.3	2.0	
	CV%	0.5	0.3	0.3	2.0	
On Board Quality Control Level 3						
Parameter	n = 20	Analyzer # 1	Analyzer # 2	Analyzer # 3	Pooled	Target Range
pH	Mean	7.563	7.554	7.563	7.560	7.549-7.599
	SD	0.001	0.002	0.002	0.005	
pCO ₂ (mmHg)	Mean	24.8	25.2	25.0	25.0	18.9-27.9
	SD	0.4	0.4	0.5	0.5	
	CV%	1.7	1.7	2.1	1.9	
pO ₂ (mmHg)	Mean	133.0	134.9	135.4	134.4	125.7-149.7
	SD	0.5	0.6	0.4	1.1	
	CV%	0.4	0.4	0.3	0.9	

Linearity Testing

10 – 14 levels were prepared by tonometry, spiking or diluting whole blood to span the analytical measurement range for each parameter. Each blood level was analyzed in duplicate on each of the three (3) test analyzers and on the Stat Profile Prime CCS Comp analyzers. The Prime CCS Comp analyzers were used to establish the target value of each blood level for each parameter. The observed values from each test analyzer were compared to the results from the comparative method.

Results: Least squares linear regression analysis of the test results vs. the reference analyzer results was performed. The data is summarized in Table 6 and contains the following information:

- slope and intercept of the fitted line
- total number of points used in the regression
- range of data
- correlation coefficient

Conclusion: The comparison data for all parameters for the Stat Profile Prime analyzers shows good correlation with the reference analyzer across the claimed measurement range for all parameters.

Table 6: Stat Profile Prime ABG Whole Blood Linearity

Individual Analyzer Performance Data						
Parameter	total # levels	Specimen Range	Analyzer	Slope	Intercept	r
pH	13	6.555 - 8.221	#1	0.9915	0.0632	0.9998
	13	6.558 - 8.250	#2	0.9948	0.0432	0.9997
	13	6.531 - 8.230	#3	0.9997	0.0006	0.9998
pCO ₂ (mmHg)	14	0.9 - 230.8	#1	1.0017	-0.5304	0.9982
	15	0.3 - 228.1	#2	0.9939	0.8671	0.9975
	15	1.0 - 229.3	#3	0.9934	2.2697	0.9990
pO ₂ (mmHg)	13	8.3 - 719.7	#1	0.9936	-1.7134	0.9994
	13	9.7 - 721.2	#2	1.0204	-1.9551	0.9996
	13	9.3 - 728.8	#3	1.0035	0.1656	0.9995

Interference Testing

As described above, the measuring technology, physical characteristics, composition, and measurement surface area of the pH, pCO₂, and pO₂ sensors of the candidate device that are in direct contact with the sample are identical to the sensors of the predicate device. The device software was changed to allow for testing of pH, pCO₂, and pO₂ only with the candidate device, but this software change did not affect the pH, pCO₂, and pO₂ measurements. Therefore, evaluation of potential interferents was not repeated for the candidate device since this study was performed previously for the predicate device in k131703.

8. Traceability

pH

The pH standards and reagents used for Nova Biomedical products are traceable to NIST primary pH reference material SRM 2186I and 2186II.

PCO₂/PO₂

PCO₂/PO₂ controls and reagents are measured against Nova Biomedical CO₂/O₂ gases traceable to NIST's SRM 2191A and 1702A.

9. Stability and Value Assignment for Internal and External Controls

Stability/Shelf Life:

- Stat Profile Prime Calibrator Cartridge ABG - 18 month shelf life for the when stored unopened.
- Stat Profile Prime Auto QC Cartridge ABG - 18 month shelf life when stored unopened at 2-8°C.
- Stat Profile Prime Ampuled Control ABG/CCS - 18 month shelf life

Value Assignment:

Stat Profile Prime Auto QC Cartridge ABG		
Lot 401741		Insert Sheet Range
Level 1	pH	7.134-7.184
	pCO ₂	52.2-67.2 mmHg
	pO ₂	50.0-66.0 mmHg
Level 2	pH	7.342-7.392
	pCO ₂	34.2-45.2 mmHg
	pO ₂	90.8-106.8 mmHg
Level 3	pH	7.549-7.599
	pCO ₂	18.9-27.9 mmHg
	pO ₂	125.7-149.7 mmHg

Stat Profile Prime Ampuled Controls ABG		
Lot 309702		Insert Sheet Range
Level 1	pH	7.118-7.168
	pCO ₂	58.6-73.6 mmHg
	pO ₂	50.2-66.2 mmHg
Level 2	pH	7.333-7.383
	pCO ₂	39.6-50.6 mmHg
	pO ₂	95.9-111.9 mmHg
Level 3	pH	7.548-7.598
	pCO ₂	19.3-28.3 mmHg
	pO ₂	121.7-145.7 mmHg

Stat Profile Prime ABG Target Calibrator Values				
	Cal A	Cal B	Cal F	Soln R
pH	7.354	6.840		
pCO ₂	25 mmHg		50 mmHg	
pO ₂			100 mmHg	
				2 mol/L KCl

10. Software Verification and Validation

The software incorporated into the Stat Profile Prime ABG Analyzer was developed and documented in compliance with the internal design control and software verification/validation procedures of Nova Biomedical.

11. Electromagnetic Compatibility and Electrical Safety

Electromagnetic Compatibility and electrical safety tests were performed on the Stat Profile Prime ABG Analyzer System to demonstrate compliance with current standards applicable to the device listed in section 12 below.

12. Standard/Guidance Documents Referenced

- CLSI EP09-A2 - Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second Edition
- NCCLS EP5-A2 - Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition
- NCCLS, EP6-A - Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline
- EN 61010-1/A2:2001 - Safety Requirements for Electrical Equipment
- EN 61010-2-081:2003 - Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
- EN 61010-2-101:2002 - Particular requirements for in vitro diagnostic (IVD) medical equipment

13. Conclusion:

The Stat Profile Prime ABG Analyzer System is substantially equivalent to the previously cleared for market Stat Profile Prime CCS Analyzer System in intended use. It uses the same sensor technology and measurement algorithms for pH, PCO₂, and PO₂, and the formulations of the internal and external controls and the calibration cartridge are the same for the tested parameters

The results of software validation and performance verification testing confirmed that the Stat Profile Prime ABG Analyzer is safe and effective for its intended purpose and that the Stat Profile Prime ABG Analyzer System is substantially equivalent to that of the predicate Stat Profile Prime CCS Analyzer System (K131703).